

URGENT FIELD SAFETY NOTICE**AMH Gen II ELISA (REF A79765)**

Part Number	Kit Lot Number
A79765	All Lots

Dear Beckman Coulter AMH Gen II Customer,

Beckman Coulter is initiating a field safety corrective action for the product listed above. This letter contains important information that needs your immediate attention regarding the measurement of Anti-Müllerian Hormone (AMH) using the AMH Gen II ELISA kit.

ISSUE:

Beckman Coulter has confirmed through customer feedback and internal investigation that some samples diluted with the AMH Gen II Sample Diluent prior to running the assay may generate results that are falsely elevated.

IMPACT:

- For samples that are diluted prior to running the assay, test results may exceed their true value by approximately two-fold.
- For samples that are not diluted, there is no impact on test results and a retrospective review of your results is not required.

ACTIONS/RESOLUTION:

- **Do not** dilute AMH samples prior to running the assay.
- For any value generated that exceeds the stated limit of the highest AMH Gen II ELISA Calibrator, report this value as a greater than value (e.g. > 22.5 ng/mL). Do not attempt to dilute this sample, as the test results may exceed the expected value by approximately two-fold.
- At the discretion of the Laboratory Director, notify Clinicians/Research Scientists of possible affected sample results.

The national competent authority has been informed of this field safety corrective action.

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected products listed in the table to another laboratory, please provide a copy of the letter to them.

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact Technical Support.



We apologize for the inconvenience that this has caused your laboratory.



VP, Quality and Regulatory Affairs

Enclosure: Response Form

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